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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: The inventions listed below are owned by an agency of the U.S.

Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Java Software for Investigational Drug Clinical Research

Description of Technology: A Java based software application available for academic use and on a royalty-bearing basis for commercial licensing. The Investigational Drug Management System (IDMS) supports the operational needs of the investigation drug section of a pharmacy providing inventory management functions which fulfill the record-keeping requirements defined in the Code of Federal Regulations related to the storage, labeling, handling, and dispensing of investigational drugs. The internet/browser based application interfaces with the Computerized Provider Order Entry (CPOE) system for tracking patients and prescriptions for investigational drugs. The IDMS supports the prescription filling process by capturing real-time data during the dispensing activity where automated safety checks are performed, ensuring the “five rights” of medication use are satisfied. The system supports randomized double-blind clinical trials by generating complex, multi-tiered randomization schemes that produce patient-specific treatment assignments along with industry standard labels containing barcodes. IDMS serves as the book of record providing end-to-end traceability for the receipt of raw materials from their source to the dispensing of finished pharmaceutical dosage forms to patients.

Potential Commercial Applications:

- Clinical data management
- Clinical Trials
- Investigational new drug trials

Competitive Advantages:

- Web based

- User friendly
- Data portability
- Randomization tables

Development Stage:

- Prototype
- Clinical

Inventors: Richard O. DeCederfelt, George J. Grimes, Stephen M. Bergstrom, Jon W. McKeeby (all of NIH-CC)

Intellectual Property: HHS Reference No. E-063-2013/0 – Research Tool.

Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301-435-5019;

shmilovm@mail.nih.gov

Software to Improve the Quality of Microscopy Images

Description of Technology: Available for licensing and commercial use is software based on an iterative deconvolution procedure that recovers images that have been blurred by a known point spread function. The software provides superior results when multiple independent observations of the same specimen are obtained. An example of such observations might be the multiple views of a specimen collected by a selective illumination plane microscope (SPIM). By using the blurring function and observations (raw images) corresponding to each view in sequential order through the iteration loop, the resulting output contains higher resolution, contrast, and signal than would result if any single observation alone was used, or if the output from single deconvolution

operations on each image are combined, e.g. by averaging. In its current form, the software has been tested on the Richardson-Lucy deconvolution (RLD) procedure. Preliminary data indicate that the algorithm provides an isotropic resolution of 350 nm, greatly improving the raw data (lateral resolution 0.5 microns, axial resolution 1.5 microns) on nematode embryos. In vivo data illustrating the power of the algorithm are available upon request.

Potential Commercial Applications:

- Image Resolution
- Sub-micron microscopy

Competitive Advantages:

- Enables isotopic resolution
- Iterative deconvolution algorithm that can readily be applied to SPIM datasets

Development Stage:

- Prototype
- In vitro data available
- In vivo data available (animal)

Inventors: Hari Shroff, Andrew York, Yicong Wu (all of NIBIB)

Publications:

1. Swoger J, et al. Multi-view image fusion improves resolution in three-dimensional microscopy. *Opt Express*. 2007 Jun 25;15(13):8029-42. [PMID 19547131]
2. Verveer PJ, et al. High-resolution three-dimensional imaging of large specimens with light sheet-based microscopy. *Nat Methods*. 2007 Apr;4(4):311-3. [PMID 17339847]

Intellectual Property: HHS Reference No. E-062-2013/0 – Software Tool.

Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301-435-5019;

shmilovm@mail.nih.gov

Collaborative Research Opportunity: The NIBIB Section on High Resolution Optical Imaging is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize our algorithm, especially with respect to multiview microscopes. For collaboration opportunities, please contact Hari Shroff at hari.schroff@nih.gov.

Background-Free Fluorescent Nanodiamond Imaging

Description of Technology: Available for licensing and commercial development are intellectual property rights covering a method of imaging a biological specimen (e.g., human tissue) using fluorescent nanodiamonds implanted into the subject of interest, applying a magnetic field to said subject and producing a resultant image by a net juxtaposition of a second acquired image. This process suppresses the background and permits selective imaging of the nanodiamonds in the presence of background fluorescence that exceeds the signal from the nanodiamonds. Another aspect of the invention provides an imaging method in which the resulting image is acquired by applying time-varying magnetic fields using one or more secondary image averaged against the first. The technique relies on imposing a small (~100 Gauss) magnetic field on the sample of interest during optical imaging combined with post-processing of the acquired images to remove the background. This technology can readily be added onto

any commercial optical imaging platform to achieve background-free images of the nanodiamonds in a biological specimen.

Potential Commercial Applications:

- In vitro and in vivo optical imaging and diagnostics
- MRI imaging

Competitive Advantages:

- Improved resolution through composite imagery
- Background elimination
- Indefinite tracking due to the exceptional stability of the fluorescent

nanodiamonds

- Wide excitation band (~500-600 nm)
- Broad-band Near IR emission (600-700 nm)
- Nanodiamonds are stable in aqueous solution
- In related technologies we have developed a method to specifically coat and

functionalize nanodiamonds for targeting and labeling applications

Development Stage:

- Prototype
- In vitro data available
- In vivo data available (animal)

Inventors: Susanta Sarkar, Ambika Bumb, Keir Neuman (all of NHLBI)

Intellectual Property: HHS Reference No. E-261-2012/0 – US Provisional

Application No. 61/711,702 filed 09 Oct 2012

Related Technology: HHS Reference No. E-175-2012/0 – US Provisional Application No. 61/672,996 filed 18 Jul 2012, "Method of Preparing Silica-coated Nanodiamonds"

Licensing Contact: Michael Shmilovich; 301-435-5019;
shmilovm@mail.nih.gov

Collaborative Research Opportunity: The NHLBI Laboratory of Single Molecule Biophysics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize background-free imaging of fluorescent nanodiamonds for in vivo and in vitro applications. For collaboration opportunities, please contact Keir C. Neuman, Ph.D. at neumankc@mail.nih.gov or 301-496-3376.

Silica-Coated Nanodiamonds for Imaging and the Delivery of Therapeutic Agents

Description of Technology: NIH investigators invented a robust and easily implemented method of synthesizing silica-coated nanodiamonds for imaging and therapeutic applications. A patent estate covering these methods is offered for licensing to commercial entities. The method generally includes coating nanodiamonds with a silica precursor, e.g., tetraethylorthosilicate (TEOS), inside liposomes. The liposomes are then removed to yield a final product that is stable, monodisperse, and easy to functionalize.

Potential Commercial Applications:

- Imaging
- Drug delivery

Competitive Advantages:

- Small size
- Physiologically inert carrier
- Monodisperse
- Stable in aqueous solution
- Readily functionalized

Development Stage: Prototype

Inventors: Ambika Bumb (NHLBI), Susanta Kumar Sarkar (NHLBI), Keir Neuman (NHLBI), Martin Brechbiel (NCI)

Publications:

1. Yu SJ, et al. Bright fluorescent nanodiamonds: no photobleaching and low cytotoxicity. J Am Chem Soc. 2005 Dec 21;127(50):17604-5. [PMID 16351080]
2. Wilson RM. Nanodiamonds are promising quantum probes of living cells. Phys Today 2011 Aug;64(8):17. [doi 10.1063/PT.3.1204]
3. Chow EK, et al. Nanodiamond therapeutic delivery agents mediate enhanced chemoresistant tumor treatment. Sci Transl Med. 2011 Mar 9;3(73):73ra21. [PMID 21389265]
4. Krueger A. New carbon materials: biological applications of functionalized nanodiamond materials. Chemistry 2008;14(5):1382-90. [PMID 18033700]

Intellectual Property: HHS Reference No. E-175-2012/0 – US Provisional Application No. 61/672,996 filed 18 Jul 2012

Related Technology: HHS Reference No. E-261-2012/0 – US Provisional Application No. 61/711,702 filed 09 Oct 2012, "Imaging Methods and Computer-Readable Media for Background-Free imaging of Fluorescent Nanodiamonds"

Licensing Contact: Michael Shmilovich; 301-435-5019;
shmilovm@mail.nih.gov

Collaborative Research Opportunity: The NHLBI Laboratory of Single Molecule Biophysics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize fluorescent nanodiamonds for use as in vivo and in vitro optical tracking probes. For collaboration opportunities, please contact Keir C. Neuman, Ph.D. at neumankc@mail.nih.gov or 301-496-3376.

February 20, 2013
Date

Richard U. Rodriguez, M.B.A.
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National Institutes of Health

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